JAN 18 2005 K040103 1/2

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Electronic Design & Manufacturers

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BHC International Ltd.

Smart Peel™ Skin Exfoliation Technology

Derma - Light Coloured Light Therapy

World leaders of Innovative Technology
Skin Resurfacing & Rejuvenation Equipment

510(k) Summary of safety and Effectiveness for the Soundskin Phototherapy System

This 510(k) Summary of safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92

1. *General Information*

Submitter	*BHC International Ltd* *18 Stapledon Road* *Orton Southgate* *Peterborough* *PE2 6TD* *United Kingdom*
Contact Person	*Michael Breen* *400 Lathrop Avenue* *Suite 200* *River Forest* *IL 60305* *USA* *Tel: 708 366 6626* *Fax: 708 366 5655*
Summary Preparation Date	*Wednesday, 20 October 2004*

2. *Names*

Device Name:	*Soundskin Phototherapy System*
Classification Name	*Laser Instrument, Surgical Powered* *Product Code: GEX* *Panel: 79*

3. *Predicate Devices*

The Soundskin Phototherapy System is substantially equivalent to the Lumenis Clearlight (K013623)

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4. *Device Description*

The Soundskin Phototherapy System is a visible light source of high spectral purity, it provides uniform illumination of red light and blue light within the same lamp housing. The output is pre-tuned to one wavelength for each light, with a narrow spectral bandwidth of 635 +/-5nm for red light and an output of 435 +/-5nm bandwidth for blue light. The light output is 2460 mW per sq cm of the treatment area with a lamp efficiency of 95% of the output. This compares with laser outputs which are approximately 2300-2500 mW per sq cm of area covered when measured in joules the output can average between 15 and 60J per sq cm. We have supplied technical data sheets and charts for the information requested.
The Soundskin system is in three parts, the base unit contains the power supply and electronic control unit, the programme is electronic timed through mechanical relays instead of software for simplicity and reliability. The red light runs for 10 minutes then changes to blue light for 10 minutes, at the end of the 20 minute cycle it automatically shuts off. There is a separate mains supply switch attached to the base unit and a single on off switch on the lamp housing everything is automatic operation. A three part arm attached to the base unit supports the lamp housing, the head is attached to the end of the arm with a multifunctional positioning for patient treatment. The automatic controlled electronics operate from a single reset button on the lamp housing for easy access.

5. *Indications for use*

The Soundskin Phototherapy System is generally indicated to treat dermatological conditions, specifically indicated to treat moderate inflammatory Acne Vulgaris.

6. *Performance data*

Based upon an analysis of the overall performance characteristics for the Soundskin Light device, BHC International believes that no significant differences exist between this system and the predicate system quoted. Therefore, the Soundskin Phototherapy System raises no new issues of safety and the clinical trials prove the effectiveness is the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2005

BHC International Ltd.
c/o Mr. Michael Breen
400 Lathrop Avenue, Suite 200
River Forest, Illinois 60305

Re: K040103
Trade/Device Name: Soundskin Phototherapy System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 21, 2004
Received: December 22, 2004

Dear Mr. Breen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K040103

Device Name Soundskin Phototherapy System

Indications for use

The Soundskin Phototherapy System is generally indicated to treat dermatological conditions, specifically indicated to treat moderate inflammatory Acne Vulgaris.

Prescription Use X Yes AND/OR Over-The-Counter Use No
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040103